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*Attorneys for Plaintiff Ferring B.V.*

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

FERRING B.V.,

Plaintiff,

v.

WATSON PHARMACEUTICALS, INC.,  
WATSON LABORATORIES, INC.,  
WATSON LABORATORIES, INC. -  
FLORIDA and WATSON PHARMA, INC.,

Defendants.

Case No: 2:12-cv-1935

**COMPLAINT FOR PATENT  
INFRINGEMENT**

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1 Plaintiff Ferring B.V. (“Ferring”), by way of Complaint against Defendants Watson  
2 Pharmaceuticals, Inc. (“Watson Pharms.”), Watson Laboratories, Inc. (“Watson Labs.”), Watson  
3 Laboratories, Inc. - Florida (“Watson Labs. - Fla.”) and Watson Pharma, Inc. (“Watson Pharma”)  
4 (collectively “Watson”), alleges as follows:

5  
6 **THE PARTIES**

7 1. Ferring is a corporation organized and existing under the laws of the Netherlands  
8 with its corporate headquarters at Polaris Avenue 144, 2132 JX Hoofddorp, The Netherlands.  
9 Ferring is engaged in the research, development, manufacture and sale of pharmaceutical  
10 products.

11 2. Upon information and belief, Watson Pharms. is a corporation organized and  
12 existing under the laws of the State of Nevada, having a principal place of business at Morris  
13 Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

14 3. Upon information and belief, Watson Labs. is a corporation organized and  
15 existing under the laws of the State of Nevada, having a principal place of business at 311  
16 Bonnie Circle, Corona, California 92880. Upon information and belief, Watson Labs. is a  
17 wholly-owned subsidiary of Watson Pharms.

18 4. Upon information and belief, Watson Labs. - Fla. is a corporation organized and  
19 existing under the laws of the State of Florida, having a principal place of business at 4955  
20 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Labs. - Fla. is a  
21 wholly-owned subsidiary of Watson Pharms.

22 5. Upon information and belief, Watson Pharma is a corporation organized and  
23 existing under the laws of Delaware, having a principal place of business at Morris Corporate  
24 Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief,  
25 Watson Pharma is a wholly-owned subsidiary of Watson Pharms.  
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**NATURE OF THE ACTION**

6. This is an action for infringement of United States Patent Number 8,273,795 (“the ’795 patent”), arising under the United States patent laws, Title 35, United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Watson Labs. - Fla.’s filing of an Abbreviated New Drug Application (“ANDA”) under Section 505(j) of the Federal Food, Drug and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market generic tablets containing 650 mg tranexamic acid (“Watson’s generic tranexamic acid tablets”).

**JURISDICTION AND VENUE**

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, this Court has jurisdiction over Watson Pharms. Upon information and belief, Watson Pharms. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Watson Pharms. directly, or through its wholly-owned subsidiaries, including Watson Labs., Watson Labs. - Fla. and Watson Pharma, manufactures, markets and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination of Watson’s generic tranexamic acid tablets.

9. Upon information and belief, this Court has jurisdiction over Watson Labs. Upon information and belief, Watson Labs. directly, or indirectly, manufactures, markets and sells generic drug products, including generic drug products manufactured by Watson Pharms., Watson Labs. - Fla. and/or Watson Pharma, throughout the United States and in this judicial district. Upon information and belief, Watson Labs. purposefully has conducted and continues to conduct business in this judicial district.

1           10.     Upon information and belief, this Court has jurisdiction over Watson Labs. - Fla.  
2     Upon information and belief, Watson Labs. - Fla. directly, or indirectly, manufactures, markets  
3     and sells generic drug products, including generic drug products manufactured by Watson  
4     Pharms., Watson Labs. and/or Watson Pharma, throughout the United States and in this judicial  
5     district. Upon information and belief, Watson Labs. - Fla. purposefully has conducted and  
6     continues to conduct business in this judicial district.  
7

8           11.     Upon information and belief, this Court has jurisdiction over Watson Pharma.  
9     Upon information and belief, Watson Pharma directly, or indirectly, manufactures, markets and  
10    sells generic drug products, including generic drug products manufactured by Watson Pharms.,  
11    Watson Labs. and/or Watson Labs. - Fla., throughout the United States and in this judicial  
12    district. Upon information and belief, Watson Pharma purposefully has conducted and continues  
13    to conduct business in this judicial district.  
14

15           12.     Upon information and belief, venue is proper in this judicial district under 28  
16    U.S.C. §§ 1391(c) and (d), and § 1400(b).

17                           **COUNT FOR PATENT INFRINGEMENT**

18           13.     The U.S. Patent and Trademark Office (“PTO”) issued the ’795 patent on  
19    September 25, 2012, and the ’795 patent expires on March 4, 2025. The ’795 patent claims,  
20    *inter alia*, methods of treating menorrhagia with tranexamic acid formulations. Ferring is the  
21    owner of the ’795 patent. A copy of the ’795 patent is attached hereto as **Exhibit A**.  
22

23           14.     Ferring Pharmaceuticals AS is the holder of New Drug Application (“NDA”) No.  
24    02-2430 for tranexamic acid tablets, which the FDA approved on November 13, 2009. The ’795  
25    patent is listed for NDA No. 02-2430 in the FDA’s Approved Drug Products with Therapeutic  
26    Equivalence Evaluations (“the Orange Book”).  
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1           15.     Ferring sells 650 mg dosage strengths of tranexamic acid tablets in the United  
2 States under the trademark Lysteda<sup>®</sup>.

3           16.     Upon information and belief, Watson Labs. - Fla.. filed with the FDA ANDA No.  
4 202093, under Section 505(j) of the Act, 21 U.S.C. § 355(j).

5           17.     Upon information and belief, Watson Labs. - Fla.'s ANDA No. 202093 seeks  
6 FDA approval to sell in the United States generic tranexamic acid tablets containing 650 mg of  
7 tranexamic acid intended to be generic versions of Lysteda<sup>®</sup>.

8           18.     On November 5, 2012, Ferring received a letter from Watson Labs. - Fla., dated  
9 November 5, 2012, purporting to be a Notice of Certification for ANDA No. 202093 ("Watson's  
10 notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21  
11 C.F.R. § 314.95(c).

12           19.     Watson's notice letter alleges that Watson Labs. - Fla. has submitted to the FDA  
13 ANDA No. 202093 seeking FDA approval to sell in the United States generic tranexamic acid  
14 tablets containing 650 mg of tranexamic acid intended to be generic versions of Lysteda<sup>®</sup>.

15           20.     Under 35 U.S.C. § 271(e)(2)(A), Watson Labs. - Fla. has infringed at least one  
16 claim of the '795 patent by submitting, or causing to be submitted to the FDA, ANDA No.  
17 202093 seeking approval for the commercial marketing of Watson's generic tranexamic acid  
18 tablets before the expiration date of the '795 patent.

19           21.     Upon information and belief, ANDA No. 202093 seeks approval of Watson's  
20 generic tranexamic acid tablets that are the same, or substantially the same, as Lysteda<sup>®</sup>.

21           22.     Upon information and belief, Watson's generic tranexamic acid tablets will, if  
22 approved and marketed, infringe at least one claim of the '795 patent.  
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1           23.     Upon information and belief, Watson Labs. - Fla. will, through the manufacture,  
2 use, import, offer for sale and/or sale of Watson's generic tranexamic acid tablets, contributorily  
3 infringe and/or induce infringement of at least one claim of the '795 patent.

4           24.     Upon information and belief, Watson Labs. - Fla.'s actions relating to ANDA No.  
5 202093 complained of herein were done with the cooperation, the participation, the assistance of,  
6 and at least in part for the benefit of, Watson Pharms., Watson Labs. and Watson Pharma.

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8           **WHEREFORE**, Plaintiff Ferring respectfully requests that the Court enter judgment in  
9 its favor and against Defendants Watson Pharms., Watson Labs., Watson Labs. - Fla. and  
10 Watson Pharma on the patent infringement claims set forth above and respectfully requests that  
11 this Court:

- 12           1)     enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Watson has infringed at  
13 least one claim of the '795 patent through Watson Labs. - Fla.'s submission of  
14 ANDA No. 202093 to the FDA to obtain approval for the commercial  
15 manufacture, use, import, offer for sale and/or sale in the United States of  
16 Watson's generic tranexamic acid tablets before the expiration of the '795 patent;  
17  
18           2)     order that the effective date of any approval by the FDA of Watson's generic  
19 tranexamic acid tablets be a date that is not earlier than the expiration of the '795  
20 patent, or such later date as the Court may determine;  
21  
22           3)     enjoin Watson from the commercial manufacture, use, import, offer for sale  
23 and/or sale of Watson's generic tranexamic acid tablets until the expiration of the  
24 '795 patent, or such later date as the Court may determine;  
25  
26           4)     enjoin Watson and all persons acting in concert with Watson from seeking,  
27 obtaining or maintaining approval of Watson Labs. - Fla.'s ANDA No. 202093  
28 until the expiration of the '795 patent;

- 1           5)       declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and  
2               award Ferring costs, expenses and disbursements in this action, including  
3               reasonable attorneys fees; and  
4  
5           6)       award Ferring such further and additional relief as this Court deems just and  
6               proper.

7       DATED this 9<sup>th</sup> day of November, 2012.

8                               GORDON SILVER

9                               By:           /s/ Molly Malone Rezac          

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**TABLE OF EXHIBITS**

<b>Exhibit</b>	<b>Exhibit Description</b>	<b>Pages<sup>1</sup></b>
<b>A</b>	Copy of the '795 patent	

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<sup>1</sup> Exhibit page count is exclusive of exhibit slip sheets.